5. 510(k) Summary

510(k) Number: k103364

MAY - 6 2011

Applicant: Diamond Diagnostics, Inc.
333 Fiske Street
Holliston, MA 01746

Contact Person: Liann Voo
Director, QA and Scientific Development
Phone: (508) 429-0450 ext. 351
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Date Prepared: March 18, 2011

Classification Name: Assayed Quality Control Material

Trade Name: Mission CliniCheck Assayed Chemistry Control

Device Classification: 21 CFR 862.1660

Device Class: Class I (Controls)

Classification Panel: CliniCheck Chemistry

Product Code: JJY

Intended Use: **Mission CliniCheck Controls** is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the following analytes Acid Phosphatase (Total), Alanine Aminotransferase (ALT/GPT), Albumin, Alkaline Phosphatase (ALP), Alpha Hydroxybutyrate Dehydrogenase (α-HBDH), Amylase, Apolipoprotein A-1, Aspartate Aminotransferase (AST/GOT), Bilirubin (Direct), Bilirubin (Total), C3 Complement, C4 Complement, Calcium, Carbon Dioxide (CO2), Chloride, Cholesterol (Total), HDL-Cholesterol, LDL-Cholesterol, Cholinesterase, Creatine Kinase (CK), Creatinine, Gamma Glutamyltransferase (GGT), Glucose, Immunoglobulin A (IgA), Immunoglobulin G (IgG), Immunoglobulin M (IgM), Iron, Iron Binding Capacity, Total (TIBC), Iron Binding Capacity, Unsaturated (UIBC), Lactate (Lactic acid), Lactate Dehydrogenase (LDH), Lipase, Lithium, Magnesium, Phosphorus, Potassium, Protein-Total, Salicylate, Sodium, T_3 Free, T_3 Total, T_4 Free, T_4 Total, Thyroid Stimulating Hormone (TSH), Transferrin, Triglycerides, Urea, Urea Nitrogen, and Uric Acid on instruments listed in the expected values chart.

Device Description: **Mission CliniCheck Assayed Chemistry Control** is a human serum based product containing constituents of purified biochemicals (tissue extracts of human and animal origin), chemicals, preservatives and stabilizers. Two levels of Control are provided in a lyophilized form. Each level is packaged into a glass amber bottle containing 5mL of product. The product is packaged in single level boxes (12 x 5mL) or multiple level boxes (6 x 2 x 5mL) and stored at 2 - 8°C.
All human source material was tested and found negative by FDA approved methods for HBsAG, HCV, and HIV-1/2.

Predicate Device Name: Mission CliniCheck Assayed Chemistry Control, Levels 1 and 2

Predicate 510(k) number(s): k093492

Comparison with Predicate Device:

Similarities

	DEVICE	PREDICATE DEVICE
Characteristics	Mission CliniCheck Assayed Chemistry Control, k103364	Mission CliniCheck Assayed Chemistry Control, K093492
PN	DD-93001D, DD-93002D	Same
Intended Use	For *in vitro* diagnostic use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the following analytes Acid Phosphatase (Total), Alanine Aminotransferase (ALT/GPT), Albumin, Alkaline Phosphatase (ALP), Amylase, Aspartate Aminotransferase (AST/GOT), Bilirubin (Direct), Bilirubin (Total), Calcium, Carbon Dioxide (CO2), Chloride, Cholesterol (Total), HDL-Cholesterol, LDL-Cholesterol, Cholinesterase, Creatine Kinase (CK), Creatinine, Gamma Glutamyltransferase (GGT), Glucose, Iron, Iron Binding Capacity, Unsaturated (UIBC), Lactate (Lactic acid), Lactate Dehydrogenase (LDH), Lipase, Lithium, Magnesium, Phosphorus, Potassium, Protein-Total, Salicylate, Sodium, Transferrin, Triglycerides, Urea, Urea Nitrogen, and Uric Acid on instruments which are listed in the expected values chart.	Same
Matrix	Serum	Same
Form	Lyophilized	Same
Levels	Two	Same
Storage	2-8°C	Same
Reconstituted Stability	20 days at -20°C	Same
Shelf Life	24 months	Same

Differences

Characteristics	Mission CliniCheck Assayed Chemistry Control	Predicate
Constituents	Contains values for Alpha Hydroxybutyrate Dehydrogenase (α-HBDH), Apolipoprotein A-1, C3 Complement, C4 Complement, Immunoglobulin A (IgA), Immunoglobulin G (IgG), Immunoglobulin M IgM), Iron Binding Capacity, Total (TIBC), T3 Free, T3 Total, T4 Free, T4 Total, Thyroid Stimulating Hormone (TSH).	Does not contain values for Alpha Hydroxybutyrate Dehydrogenase (α-HBDH), Apolipoprotein A-1, C3 Complement, C4 Complement, Immunoglobulin A (IgA), Immunoglobulin G (IgG), Immunoglobulin M IgM), Iron Binding Capacity, Total (TIBC), T3 Free, T3 Total, T4 Free, T4 Total, Thyroid Stimulating Hormone (TSH).
Packaging	12 x 5 mL	10 x 5 mL

Substantial Equivalence Table of Product Part Numbers & Trade Names

Diamond/Mission Product	Diamond/Mission Product
DD-93001 Mission CliniCheck Assayed Chemistry Control, Level 1	DD-93001 Mission CliniCheck Assayed Chemistry Control, Level 1
DD-93002 Mission CliniCheck Assayed Chemistry Control, Level 2	DD-93002 Mission CliniCheck Assayed Chemistry Control, Level 2
DD-93012 Mission CliniCheck Assayed Chemistry Control, Dual Level	DD-93012 Mission CliniCheck Assayed Chemistry Control, Dual Level

Assessment of Non-Clinical Performance Data:

Tests were conducted to verify specific performance requirements:

- Accelerated (high temperature) stress test was done and results support a 2 year shelf life.
- Use life stability testing at -20°C supports a 20 day life.
- Use life stability testing under refrigerated (2-8°C) conditions support a 7 day life.

Assessment of Clinical Performance Data:

NA

Conclusions:

Comparison of technological characteristics, formulation and intended use to predicate device listed in this summary support the claim of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

MAY 6 2011

Diamond Diagnostics, Inc.
c/o Liann Voo, Director, Quality Assurance and Scientific Development
333 Fiske Street
Holliston, MA 01746

Re: k103364
Trade Name: Mission CliniCheck Assayed Chemical Control
Regulation Number: 21 CFR §862.1660
Regulation Name: Quality Control Material (assayed and unassayed)
Regulatory Class: Class I, reserved
Product Codes: JJY
Dated: March 18, 2011
Received: March 21, 2010

Dear Ms. Voo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

4. Indications for Use Statement

510(k) Number (if known): k103364

Device Name: **Mission CliniCheck Assayed Chemistry Control**

Indications For Use:

Mission CliniCheck Controls is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the following analytes, Acid Phosphatase (Total), Alanine Aminotransferase (ALT/GPT), Albumin, Alkaline Phosphatase (ALP), Alpha Hydroxybutyrate Dehydrogenase (α-HBDH), Amylase, Apolipoprotein A-1, Aspartate Aminotransferase (AST/GOT), Bilirubin (Direct), Bilirubin (Total), C3 Complement, C4 Complement, Calcium, Carbon Dioxide (CO2), Chloride, Cholesterol (Total), HDL-Cholesterol, LDL-Cholesterol, Cholinesterase, Creatine Kinase (CK), Creatinine, Gamma Glutamyltransferase (GGT), Glucose, Immunoglobulin A (IgA), Immunoglobulin G (IgG), Immunoglobulin M (IgM), Iron, Iron Binding Capacity, Total (TIBC), Iron Binding Capacity, Unsaturated (UIBC), Lactate (Lactic acid), Lactate Dehydrogenase (LDH), Lipase, Lithium, Magnesium, Phosphorus, Potassium, Protein-Total, Salicylate, Sodium, T_3 Free, T_3 Total, T_4 Free, T_4 Total, Thyroid Stimulating Hormone (TSH), Transferrin, Triglycerides, Urea, Urea Nitrogen, and Uric Acid on instruments listed in the expected values chart.

Prescription Use ____X__ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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